Minute Order Form (06/97)

United States District Court, Northern District of Illinois

Name of Assigned Judge or Magistrate Judge	Joan H. Lefkow	Sitting Judge if Other than Assigned Judge	
CASE NUMBER	04 C 2436	DATE	10/7/2004
CASE TITLE	Teva Pharmaceuticals USA, Inc. vs. Abbott Laboratories		

[In the following box (a) indicate the party filing the motion, e.g., plaintiff, defendant, 3rd party plaintiff, and (b) state briefly the nature of the motion being presented.]

MOTION:

DOCKET ENTRY:

(1) ☐ Filed motion of [use listing in "Motion" box above.]

(2) ☐ Brief in support of motion due _____.

(3) ☐ Answer brief to motion due_____. Reply to answer brief due_____.

(4) ☐ Ruling/Hearing on _____ set for _____ at _____.

(5) ☐ Status hearing[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(6) ☐ Pretrial conference[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(7) ☐ Trial[set for/re-set for] on _____ at _____.

(8) ☐ [Bench/Jury trial] [Hearing] held/continued to _____ at _____.

(9) ☐ This case is dismissed [with/without] prejudice and without costs[by/agreement/pursuant to]
☐ FRCP4(m) ☐ Local Rule 41.1 ☐ FRCP41(a)(1) ☐ FRCP41(a)(2).

(10) ■ [Other docket entry] Enter Memorandum Opinion and Order. For the reasons stated in the Memorandum Opinion and Order, defendant's motion to dismiss for lack of subject matter jurisdiction [#21] is granted. Case dismissed.

(11) ■ [For further detail see order attached to the original minute order.]

	No notices required, advised in open court.		3 number of notices	Document Number
	No notices required.			
✓	Notices mailed by judge's staff.		OCT 12 2004 date docketed	
	Notified counsel by telephone.			
	Docketing to mail notices.		docketing deputy initials	23
✓	Mail AO 450 form.	U.S. DISTRICT COURT		
	Copy to judge/magistrate judge.		10/7/2004 date mailed notice	
MD	courtroom deputy's initials	2004 OCT -8 PM 4:06	MD mailing deputy initials	
		Date/time received in central Clerk's Office		

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

TEVA PHARMACEUTICALS USA, INC.	)	
	)	
Plaintiff,	)	
	)	
v.	)	**No. 04 C 2436**
	)	**Judge Joan H. Lefkow**
ABBOTT LABORATORIES	)	
	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

Plaintiff, Teva Pharmaceuticals USA, Inc. ("Teva"), filed this action seeking a declaratory judgment that United States Patent Nos. 5,844,105 ("the '105 patent"), 5,945,405 ("the '405 patent"), 5,858,986 ("the '986 patent"), 6,010,718 ("the '718 patent"), and 6,551,616 ("the '616 patent") held by defendant, Abbott Laboratories ("Abbott"), are invalid and would not be infringed if Teva commercially marketed a generic version of Abbott's extended release clarithromycin product, BIAXIN XL. Before the court is Abbott's Motion to Dismiss for Lack of Subject Matter Jurisdiction, claiming that no case or controversy existed at the time Teva filed its suit. For the reasons stated below, Abbott's motion is granted.

I. Factual and Procedural Background

Abbott is the exclusive licensee of United States Patent No. 4,331,803 ("the '803 patent"), a compound patent relating to clarithromycin, the active ingredient in both BIAXIN IR, Abbott's immediate release clarithromycin product, and BIAXIN XL, 's extended release clarithromycin product. The '803 patent expires on May 23, 2005. In addition to the compound

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patent, Abbott is the current holder of the '105 patent, the '405 patent, and the '986 patent, all of which relate to different crystal forms of clarithromycin. Abbott is also the current holder of the '718 and '616 patents, which relate to extended release formulations of clarithromycin.

On December 17, 2002, Teva, a developer, manufacturer, and marketer of generic pharmaceutical products, filed an abbreviated new drug application ("ANDA") seeking approval from the Food and Drug Administration ("FDA") to release a generic version of Abbott's immediate release clarithromycin product, BIAXIN IR. On the same day, Teva filed an ANDA seeking approval to release a generic version of Abbott's extended release clarithromycin product, BIAXIN XL.

On August 6, 2003, Teva filed suit in this court seeking a declaratory judgment that (1) the '105 patent, the '405 patent, and the '986 patent ("the *Teva I* patents") are invalid under 35 U.S.C. § 101, and (2) Teva's generic version of Abbott's immediate release clarithromycin product would not infringe those patents. *See Teva Pharmaceuticals USA, Inc.* v. *Abbott Laboratories*, 301 F. Supp. 2d 819 (N.D. Ill. 2004) ("*Teva I*"). *Teva I* did not involve, indeed did not mention, Teva's attempt to gain approval to release an extended release clarithromycin product, and Abbott did not learn of Teva's attempt to do so until filing of the instant suit.

Abbott filed a motion to dismiss *Teva I* for lack of jurisdiction, claiming that no case or controversy existed at the time the suit was filed, which the court denied. On March 15, 2004, Abbott filed an answer and asserted compulsory counterclaims for infringement of the *Teva I* patents. Teva filed a reply to Abbott's counterclaims on April 5, 2004.

On August 6, 2003, the same day Teva filed *Teva I*, Teva sent a letter informing Abbott of the lawsuit and asking Abbott to provide a covenant not to enforce the *Teva I* patents against

Teva's immediate release clarithromycin product. Abbott has refused to provide Teva with a covenant not to sue.

On three other occasions, Abbott has sued or maintained suit against Teva or its Canadian affiliate Novopharm Limited ("Novopharm") for patent infringement relating to other drugs for which Teva has filed ANDAs: (1) *Abbott Laboratories* v. *Novopharm Ltd.*, 00 CV 2141, 00 CV 5094, and 01 CV 1914 (N.D. Ill.), concerning fenofibrate; (2) *Abbott Laboratories, Fournier Industrie at Sante & Laboratories Fournier SA* v. *Teva Pharmaceutical Co., Inc.*, C.A. 02-1512 (D. Del.), concerning fenofibrate; and (3) *Knoll Pharmaceutical Co., Inc. and The John and Lois Arnold Family Ltd. Liab. P'Ship* v. *Teva Pharmaceuticals USA, Inc.*, 01 CV 1646 (N.D. Ill.), concerning vicoprofen.

In addition, on June 18, 2002, Novopharm served a "Notice of Allegation"[1] on Abbott and its Canadian Subsidiary, Abbott Laboratories Limited,[2] pertaining to an Abbreviated New Drug Submission ("ANDS") filed by Novopharm seeking regulatory approval to market a generic version of BIAXIN IR in Canada. In the Notice of Allegation, Novopharm asserted that the Canadian counterpart of the *Teva I* patents ("the Canadian patent") was invalid and that Novopharm's immediate release clarithromycin product would not infringe the Canadian patent. In response to the Notice of Allegation, Abbott filed a "Regulatory Application" in the Federal Court of Canada seeking an order prohibiting the Canadian Minister of Health from issuing a

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[1]Any drug manufacturer who seeks to market in Canada a generic version of a patented drug must file an Abbreviated New Drug Submission ("ANDS") with the Minister of National Health and Welfare. The ANDS must be supported by an allegation asserting that the listed drug patent would not be infringed if the applicant's submission were granted and explaining the basis for the assertion. A notice of such allegation must be served on the holder of the patent. *See Eli Lilly & Co. et al.* v. *Apotex Inc. et al.* (1997), 76 C.P.R. (3d) 1 (F.C.A.) at 3-5.

[2]For purposes of discussion regarding the Canadian proceedings, Abbott and Abbott Laboratories Limited are referred to as "Abbott."

Notice of Compliance ("NOC") to Novopharm until the Canadian patent expires.[3] Abbott has also filed Regulatory Applications against four other generic manufacturers who have challenged the Canadian patent. On October 14, 2003, Novopharm agreed to withdraw its Notice of Allegation, and Abbott in turn agreed to discontinue its Regulatory Application.

II. Requirements for Jurisdiction Under the Declaratory Judgment Act

The Declaratory Judgment Act limits issuance of a declaratory judgment to cases of "actual controversy." 28 U.S.C. § 2201(a). If no actual controversy exists between the parties regarding the subject on which declaratory judgment is sought, the court lacks subject matter jurisdiction. *Aetna Life Ins. Co.* v. *Haworth*, 300 U.S. 227, 239-40 (1937); *Spectronics Corp.* v. *H.B. Fuller Co.*, 940 F.2d 631, 634 (Fed. Cir. 1991). A declaratory judgment "may not be a medium for securing an advisory opinion in a controversy which has not arisen." *Coffman* v. *Breeze Corp.*, 323 U.S. 316, 324 (1945). Furthermore, even if a justiciable controversy has been shown to exist, federal courts have discretion to decline to exercise their jurisdiction. *International Harvester Co.* v. *Deere & Co.*, 623 F.2d 1207, 1217 (7th Cir. 1980)

In declaratory judgment actions involving allegations of patent noninfringement, invalidity, or unenforceability, an "actual controversy" exists where there is both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity by the declaratory plaintiff which could constitute infringement or concrete steps taken with the intent

[3]Under Canadian law, when an innovator company like Abbott receives a Notice of Allegation, it must commence an application for prohibition ("Regulatory Application") within 45 days, or the Minister of Health will issue an NOC to the generic manufacturer. An NOC is a prerequisite for marketing drugs. *See Eli Lilly & Co. et al.* v. *Apotex Inc. et al.* (1997), 76 C.P.R. (3d) 1 (F.C.A.) at 3-5.

to conduct such activity. *Fina Research, S.A.* v. *Baroid Ltd.*, 141 F.3d 1479, 1481 (Fed. Cir. 1998). The declaratory plaintiff bears the burden to establish, by a preponderance of the evidence, that the two-part test for an actual controversy has been met. *See McNutt* v. *General Motors Acceptance Corp.*, 298 U.S. 178, 189 (1936)("[T]he court may demand that the party alleging jurisdiction justify his allegations by a preponderance of evidence.").

In *Teva I*, the court held that Teva's submission of an ANDA under 35 U.S.C. § 355(j) for its immediate release clarithromycin product constituted an act of infringement sufficient to satisfy the second prong of the "actual controversy" test. 301 F. Supp. 2d at 830. Teva also submitted an ANDA for its extended release clarithromycin product. Thus, for the reasons set forth in *Teva I*, Teva has satisfied the second prong of the "actual controversy" test in this case.

The only issue before the court, then, is whether Abbott's actions created a reasonable apprehension on the part of Teva that it will face an infringement suit regarding its extended release clarithromycin product. To demonstrate a reasonable apprehension of suit, a declaratory plaintiff need not establish that the defendant has made an explicit threat. *Kos Pharms., Inc.* v. *Barr Labs, Inc.*, 242 F. Supp. 2d 311, 314 (S.D.N.Y. 2003). It must, however, demonstrate "conduct that rises to a level sufficient to indicate an intent [of the patentee] to enforce its patent, i.e. to initiate an infringement action." *EMC* v. *Norand Corp.*, 89 F.3d 807, 811 (Fed. Cir. 1996). The subjective impressions of the plaintiff are insufficient to satisfy the requirement. Rather, the court must find objective facts indicating the intent of the patentee to enforce its patent, considering the totality of the circumstances at the time the complaint was filed. *Arrowhead*, 846 F.2d at 736.

Teva contends that it reasonably apprehends a patent infringement suit by Abbott based on three factors: (1) Abbott commenced proceedings in Canada under the *Patented Medicines (Notice of Compliance) Regulations* ("the *PM(NOC) Regulations*") against Novopharm in connection with Novopharm's attempt to obtain approval to market a generic immediate release clarithromycin product in Canada; (2) Abbott has a history of patent enforcement against Teva concerning Teva's efforts to market generic versions of Abbott's brand name drugs, including filing compulsory counterclaims alleging infringement in *Teva I*; and (3) Abbott has refused to covenant that it will not enforce its patent rights against Teva.

With the exception of the counterclaims Abbott filed in *Teva I*, these are exactly the factors on which Teva relied to establish a reasonable apprehension of suit in *Teva I*. There is, however, a crucial difference between the two cases – they concern two different products. As Teva admits, "the formulations for Teva's Biaxin [IR] and Biaxin XL equivalents are different from each other . . . ." (Resp., at 2.) The Federal Circuit has made it clear that a declaratory relief plaintiff must establish a reasonable apprehension of suit with respect to *each* product in suit:

> Where, as here, a declaratory-judgment plaintiff attempts to ground jurisdiction on activities involving distinct, technologically different products, the court must carefully calibrate its analysis to each of the products. To do otherwise would risk issuing an advisory opinion on one product – or on a method of using that product – based on an actual controversy involving another product.

Sierra Applied Sciences v. *Advanced Energy Industries*, 363 F.3d 1361, 1374 (Fed. Cir. 2004). Carefully calibrating its analysis to Teva's extended release product, the court finds that Teva has failed to establish that it has a reasonable apprehension of suit on that product.

A brief review of the court's reasoning in *Teva I* reveals the flaw in Teva's argument. In that case, the court held that Teva reasonably apprehended an infringement suit based on two

factors, the Canadian proceedings and Abbott's history of enforcing its patent rights against Teva. The court indicated that neither of these factors, taken alone, was dispositive of a reasonable apprehension of suit. 301 F. Supp. 2d at 822 ("[F]oreign litigation, while not dispositive of a reasonable apprehension of suit in the United States, is one factor to be considered in the analysis."), 825-26 ("In combination with the Canadian proceedings, Abbott's recent history of enforcement of its patent rights against Teva and its affiliates is sufficient to create a reasonable apprehension that Abbott will initiate a patent infringement suit against Teva if Teva attempts to market a generic version of BIAXIN.").

The Canadian proceedings between Abbott and Novopharm involved the very same immediate release clarithromycin product that was at issue in *Teva I*. The Canadian proceedings did not, however, involve the extended release product at issue here. Thus, the Canadian proceedings have far less relevance in this case than they did in the earlier action. *See International Harvester Co.*, 623 F.2d at 1212 (The specific product at issue "was in no way involved in the prior suit and thus that suit cannot be viewed as anything more than a general indication that Deere considers litigation a viable alternative once it has determined that a competitor is producing a product which infringes the patent at issue here.").

Similarly, Abbott's counterclaims in *Teva I* involve only the immediate release product. The counterclaims, therefore, amount to nothing more than an additional example of prior litigation between the parties concerning different products from the one at issue here. Again, such prior litigation between the parties is relevant, but not dispositive, of a reasonable apprehension of suit. *See, e.g., International Harvester*, 623 F.2d at 1212 ("[A] prior suit is but one factors to be considered . . . ."); *Dr. Reddy's Laboratories, Ltd.* v. *AaiPharma Inc.*,

01cv10102(LAP), 2002 WL 31059289, at *8 (S.D.N.Y. 2002) (holding that three previous suits filed by defendant against plaintiff involving the manufacture of generic versions of Prozac were "additional support for [plaintiff's] reasonable apprehension of an infringement suit" regarding its attempt to manufacture a generic version of Prilosec).

Abbott's refusal to provide a covenant not to sue is simply irrelevant in this case. Teva's request for a covenant from Abbott mentioned only the immediate release product. A refusal to covenant not to sue on one product cannot provide a reasonable apprehension of suit on a different product.

In short, the only objective facts supporting Teva's apprehension of a patent infringement suit involving its extended release clarithromycin product are prior legal proceedings, in the United States and Canada, involving different products from the one at issue in this action. This is insufficient to make Teva's apprehension of suit "reasonable."

Teva points out that its generic versions of both BIAXIN IR and BIAXIN XL contain the same active ingredient. Thus, it argues that the *Teva I* patents, which relate only to the active ingredient, are equally implicated by both products and, consequently, a lawsuit on one of the products creates a reasonable apprehension of suit on the other. This argument leads directly to another basis upon which the decision reached above may be supported. Jurisdiction for a declaratory judgment action must exist with regard to each claim in suit. *Jervis B. Webb Co.* v. *S. Sys., Inc.*, 742 F.2d 1388, 1399 (Fed. Cir. 1984) ("[T]he existence of a case or controversy must be evaluated on a claim-by-claim basis."); *see also* 8 Chisum on Patents § 21.02[1][d][iii] ("The existence of an actual controversy must be evaluated on a patent by patent and claim by claim basis."). Abbott has never asserted nor threatened to assert any claims against anyone involving

the '616 and '718 patents, specific to the extended release product. Thus, Teva can have no reasonable apprehension of an infringement suit involving those patents. Any claims relating to those patents must be dismissed.

This leaves only the *Teva I* patents. *Teva I* will resolve the question of the validity of the *Teva I* patents. If the patents are ultimately found to be invalid, then the claims in this case involving the *Teva I* patents become unnecessary because Teva's extended release product "could not possibly infringe a nonexistent patent." *International Harvester*, 623 F.2d at 1218. This is an appropriate basis for the court to decline to exercise its discretionary jurisdiction. *See id.* at 1218 ("A declaratory judgment should issue only when it will serve a useful purpose. . . . the pending suit may make resolution of the issues presented by this declaratory judgment suit unnecessary."). In exercising its discretion, a federal court must consider the public interest and the plaintiff's need for the requested relief. *Id.* at 1218. The court finds that, in view of the issues pending in *Teva I*, Teva's need for declaratory relief in this case does not outweigh the interest in judicial expediency and in avoiding unnecessary court decisions. Thus, even if there is a justiciable case or controversy between the parties on the *Teva I* patents, the court declines to exercise jurisdiction.

CONCLUSION

For the reasons stated above, Abbott's Motion to Dismiss is granted [#21]. This case is terminated.

ENTER:

JOAN HUMPHREY LEFKOW
United States District Judge

Dated: October 7, 2004